DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 31, 2016

AngioScore, Inc.
c/o Kimberley Kline
Regulatory Affairs Manager
5055 Brandin Court
Fremont, CA 94538

Re: K122685
Trade/Device Name: AngioSculpt® PTA Scoring Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: January 04, 2013
Received: January 07, 2013

Dear Ms. Kline:

This letter corrects our substantially equivalent letter of January 11, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Misti L. Malone -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

AngioScore

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122685

Device Name: AngioSculpt® PTA Scoring Balloon Catheter

Indications for Use:

The AngioSculpt PTA Scoring Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, infra popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122685

K122685

JAN 11 2013

510(k) Summary for the AngioSculpt Scoring Balloon Catheter

1. Submitter's Name / Contact Person

Submitter:	AngioScore, Inc. 5055 Brandin Court Fremont, CA 94538
Contact Person:	Alison Schlosser Regulatory Affairs Specialist II Phone: 510-933-7936 Fax: 510-933-7994

Summary Preparation Date: November 21, 2012

2. General Information

Trade Name:	AngioSculpt® PTA Scoring Balloon Catheter
Common / Usual Name:	Angioplasty catheter
Classification Name:	Percutaneous catheter
Product Codes:	DQY and LIT
Predicate Devices:	AngioSculpt® Scoring Balloon Catheter (K101735/K112182)

3. Intended Use / Indications

The AngioSculpt PTA Scoring Balloon Catheter is intended for the dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, infra popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

4. Device Description

The AngioSculpt catheter is a standard two-lumen catheter with a scoring balloon near the distal tip. The distal end of the catheter has a conventional nylon-blend balloon with a scoring element that wraps around the balloon. The scoring element creates focal concentrations of dilating force which minimizes balloon slippage and assists with luminal expansion of stenotic arteries. The balloon has radiopaque markers to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at a specific pressure.

5. Technological Characteristics

The AngioSculpt catheters as compared to the 510(k) cleared AngioSculpt catheter family (K101735/K112182) incorporate substantially equivalent design, dimensional, and performance specification as the predicate catheters with the following changes:

- the smallest diameter AngioSculpt balloon sizes (2.0-3.5mm) are now available in the longest AngioSculpt balloon length (100mm),
- the distal tip of the subject catheter was modified to a tapered profile and the nominal length extended. The distal extrusion and soft tip used to form the distal bond and distal tip are replaced with a molded tip comprised of already approved AngioSculpt materials,
- a different material blend was used for the Intermediate Extrusion (a component of the Intermediate Bond); a slightly more elastic polymer was used for ease of manufacturability. The polymer is currently used in the strain relief of the device (a component of the proximal end).

6. Summary of Bench Testing

Mechanical testing of the AngioSculpt catheter was conducted in accordance with AngioScore's Risk Analysis and all applicable FDA guidance documents and relevant standards.

The following bench tests were conducted to verify that design outputs met design requirements and to confirm proper function and durability. Test articles consisted of finished sterilized catheters.

- Catheter Diameter and Balloon Profile
- Device Burst Strength(RBP)
- Balloon Compliance (Diameter vs. Pressure)
- Balloon Inflation and Deflation Time
- Device Fatigue
- Bond (Tensile) Strength
- Tip Pull Strength
- Catheter Diameter and Balloon Profile (with Scoring Element)
- Flexibility and Kink
- Torque Strength
- Pushability, Trackability and Secure Edges
- Balloon Preparation, Deployment and Retraction

- Freedom from Stent Interference
- Focal Force
- Corrosion Resistance

7. Summary of Biocompatibility Testing

The AngioSculpt catheter is categorized as an "External communicating device in contact with circulating blood with limited exposure time". The biocompatibility of the device was assessed in accordance with ISO 10993-1:2009 – *Biological evaluation of medical devices, Part 1 – Evaluation and tests within a risk management process.* In addition, the product complies with the requirements identified in *FDA Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers and Intravascular Stents(2008) – Biocompatibility testing for all interventional cardiology devices.*

Biocompatibility tests were not conducted as part of this device modification. Materials were shown to be equivalent to currently marketed AngioScore products. Biocompatibility testing confirmed that the AngioSculpt catheter is non-cytotoxic, non-sensitizing, non-irritating, not systemically toxic, and non-hemolytic when evaluated under the respective test conditions. As a conservative measure Thrombosis (*in-vivo*), was conducted in accordance with the provisions of the FDA GLP regulations 21 CFR Part 58. Thrombogenicity was evaluated as part of a GLP animal study. No thrombo-embolism was observed.

8. Summary of Animal Testing

An acute GLP and non GLP study was conducted to determine the safety and deliverability of the AngioSculpt catheter. The studies were conducted in the Ilio-femoral peripheral arteries of one experimental animal. The catheter was evaluated on deliverability (pushability and trackability), passability, device inflation and deflation parameters, overall radiopacity, and device removal.

The study results demonstrated that the AngioSculpt catheter was successfully introduced using standard guidewires in combination with a 5F sheath or 6F guide catheter and a 6F sheath or 0.079"/2.0 mm guide catheter and expanded in the targeted tissue while demonstrating no evidence of dissection, perforation, embolization, or thrombosis. All devices maintained integrity with no loss of components during the procedure. All treatment procedures were performed with ease and no adverse events occurred in any of the animals.

The objectives of the study were met. The catheters evaluated in the peripheral (femoral) arteries were found to be clinically acceptable.

9. Substantial Equivalence Comparison

The subject catheters share the same intended use, principles of operation, overall technical and functional capabilities, packaging and sterilization process, and similar design and materials as the predicate AngioSculpt catheters and are therefore substantially equivalent.

Although there are minor differences between the subject catheters and its predicate devices those differences do not raise new questions of safety or efficacy. Design verification and validation testing demonstrated adequate device performance and confirmed that no new questions of safety or effectiveness for peripheral balloon angioplasty devices were raised. The changes to the subject catheters do not affect the intended use of the device, alter the fundamental scientific technology of the device, or raise new issues of safety and effectiveness. The subject AngioSculpt PTA Scoring Balloon Catheters are therefore, substantially equivalent to the predicate catheters.